

## **DETAILED ACTION**

Petition for review has been received. Examiner acknowledges receipt of amendment and remarks filed 1/23/08. Claims 1-4 are amended. New claim 9 is added. Claims 1-8 are pending, claims 5-8 are withdrawn from consideration, and claims 1-4 and 9 are examined.

**Previous rejections that are not reiterated herein are withdrawn.**

This office action is made non-final in order to address claim 4 and applicant's chemotherapeutic drug of "nitros-metyl-urea."

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-4 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection necessitated by the amendment filed 1/23/08.

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4. The original specification does not envision/support the new recitations:
  - a) "principe selective cancer"
  - b) "killing specific type of cancer"
5. Claims 1-4 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what "principe of selective cancer cell" is in claim 1.

It is also unclear what "polyion polymer formed is a line from hundred of units" mean in claim 3.

Claim 4 is indefinite because it is not known what the compound "nitros-methyl-urea."

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-3 remain rejected under 35 U.S.C. 102(b) as being anticipated by Sakurada et al. (US 6,190,680) according to the rejections on record and reiterated herein below.

Sakurada is contemplated for aqueous compositions for delivery of chemotherapeutic agents in the presence of polyhydric alcohols (abstract). One of the polymers is polydextrose (column 3, line 33), which meets the requirement for polyion polymer. Glucose, sucrose and lactose (column 4, lines 47-49) are some of the polyhydric alcohols named. Since the

composition is an aqueous composition, it flows that the glucose is in solution meeting the requirement of claim 1. Examples of drugs in the composition are mitomycin, adriamycin, vinblastine sulfate, which meet the limitation of chemotherapeutic agent of claim 1. Claims 2 and 3 recite the properties/characteristic/intended use of the composition so that the claims are met.

### ***Response to Arguments***

8. Applicant's arguments filed 1/23/08 have been fully considered but they are not persuasive.

With regards to the art rejections:

i) *Applicant argues that the amendment to claim 1 where a combination of glucose, chemotherapeutic agent and polyion is infused to the cancer cells for release of the drug that would kill the cancer cells overcomes the art rejection, but the claims are directed to product and the prior art product comprising polydextrose, anticancer agent and glucose is capable of performing that function.*

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakurada et al. (US 6,190,680) in view of applicant's disclosure.

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11. Sakurada is described above as anticipating claims 1-3 by teaching aqueous compositions for delivery of chemotherapeutic agents such as mitomycin, adriamycin, vinblastine sulfate (column 3, lines 48 and 50) in the presence of polyhydric alcohols (abstract). One of the polymers is polydextrose (column 3, line 33), which meets the requirement for polyion polymer. Glucose, sucrose and lactose (column 4, lines 47-49) are some of the polyhydric alcohols named. Sakurada does not teach the chemotherapeutic agent recited in claim 4. However applicant's specification at page 5, line 9 identifies nitros-metyl-urea as a chemotherapeutic agent; and one chemotherapeutic agent can be used in place of the other. Therefore, taking the teaching of the reference and applicant's knowledge of nitro-metyl-urea, one having ordinary skill in the art at the time the invention was made would have reasonable expectation of success that the chemotherapeutic agent of claim 4, just like the other chemotherapeutic agents would be effectively delivered.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/

Examiner, Art Unit 1618